December 31, 2003

Donald A. Lederer
Product Stewardship Manager
Solutia, Inc.
575 Marysville Centre Drive
St. Louis, MO 63141

Dear Mr. Lederer:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Phosphoric Acid, Dibutyl Phenyl Ester posted on the ChemRTK HPV Challenge Program Web site on August 19, 2003. I commend Solutia, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Solutia, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Phosphoric acid dibutyl phenyl ester

Summary of EPA Comments

The sponsor, Solutia Inc., submitted a test plan and robust summaries to EPA for phosphoric acid dibutyl phenyl ester (dibutyl phenyl phosphate, DBPP; CAS No. 2528-36-1) dated July 24, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on August 19, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to double check the melting point and boiling point values.

2. Environmental Fate. The submitter needs to provide measured biodegradation data. If necessary, the submitter needs to recalculate fugacity using more accurate boiling and melting point values.

3. Health Effects. Available data for acute, repeated-dose, gene mutation, and reproductive/developmental toxicity endpoints are adequate for the purposes of the HPV Challenge Program. EPA reserves judgement on the chromosomal aberration endpoint because information on positive controls is lacking. The submitter needs to address a few deficiencies in the robust summaries.

4. Ecological Effects. Available data are adequate for the purposes of the HPV Challenge Program. The submitter needs to add information to the robust summary for algae.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Dibutyl Phenyl Phosphate Challenge Submission

Chemical Identification

Although the submission is for DBPP, the sponsor states that the commercial substance consists of 70 % DBPP, 15 % tributyl phosphate (TBP), and 15 % tributyl phosphate (BDPP). These proportions are said to remain essentially constant as determined by the manufacturing process. The submitter intends BDPP to refer to the mixture, but some of the data were obtained on relatively pure BDPP. Although this distinction is clear in the data summaries, it would be useful to show it in the test plan as well.

In most cases the submitter does not discuss possible effects on the endpoints by the minor components.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for vapor pressure, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Melting point. The submitter provided an estimated melting point value of 87.5 °C for DBPP. This value is unexpected because DBPP is a liquid at room temperature, and the melting points of TBP and triphenyl phosphate are -79 °C and 50-52 °C, respectively (Aldrich Handbook of Fine Chemicals and Laboratory Equipment, 2003-2004, p.1807, 1878). The submitter needs to double check its melting point value with

more reliable literature sources, or provide measured melting point data for pure dibutyl phenyl phosphate following OECD guidelines.

Boiling point. The submitter provided a boiling point of 131 - 132 °C for dibutylphenyl phosphate in table 2 on page 9 of the test plan. Using Beilstein, EPA located two reduced-pressure boiling point ranges, 125 - 125.5 °C (0.1 mm Hg) and 136 -140 °C (0.3. mm Hg), that strongly indicate that the boiling point given by the submitter is a reduced-pressure value. Using NOMO5, these boiling points correspond to normal boiling points of 358 and 358.7 °C, respectively. Therefore, the submitter needs to determine the pressure at which its boiling point value was measured and use the data to estimate a normal boiling point for the compound.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

The data provided by the submitter for photodegradation and stability in water are adequate for the purposes of the HPV Challenge Program.

Biodegradation. The submitter provided biodegradation data from two studies. The river die-away data are for primary degradation and therefore are not informative with respect to ultimate degradation. The SCAS data submitted for DBPP and TBP provide no information on ready biodegradability, since SCAS tests are by definition inherent biodegradation tests characterized by extremely high degradation potential. The submitter needs to provide ready biodegradation data following OECD TG 301.

Fugacity. The submitter may need to recalculate fugacity using more accurate boiling melting point values.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Available data for acute, repeated-dose, gene mutation, and reproductive/developmental toxicity endpoints are adequate for the purposes of the HPV Challenge Program. The submitter needs to address a few deficiencies in the robust summaries.

Acute Toxicity. An acute oral toxicity study pre-dated GLP and OECD guidelines. The methods were generally consistent with OECD TG 401 except that the group size was 5-6 mixed sex/group rather than 5/sex/group; however, the group size is reasonably consistent with the latest OECD guidelines, which call for 3/sex/group.

Chromosomal Aberrations. The adequacy of this study could not be determined because positive control information was not provided in the robust summary. EPA therefore reserves judgement on this endpoint pending receipt of additional information.

Ecological Effects (fish, invertebrates, and algae).

Available data are adequate for all acute and chronic endpoints for the purposes of the HPV Challenge Program. The submitter needs to add information to the robust summary for algae.

Specific Comments on the Robust Summaries

Health Effects

Repeated-Dose Toxicity. A robust summary for a 90-day oral toxicity bioassay was missing the magnitude of body weight effects.

Genetic Toxicity. The summary for the study conducted in 1977 neglected to include a reference citation and did not explicitly state the results of the yeast study.

A robust summary for a chromosomal aberration assay in rats exposed by intraperitoneal injection was missing information on positive controls and did not define all acronyms.

Reproductive/Developmental Toxicity. A robust summary for a two-generation reproductive toxicity assay was missing the magnitude of the treatment-related reductions in body weight.

Ecological Effects

Algae. Water hardness needs to be provided in the robust summary.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.